



# DANMAR PRODUCTS, INC.

221 JACKSON INDUSTRIAL DRIVE • ANN ARBOR, MI. 48103 U.S.A.

## 510(k) SUMMARY

Danmar Products, Inc.

Danmar Products Michigan Cranial Helmet

November 22, 2000

### Submitter Information:

Danmar Products, Inc.  
221 Jackson Industrial Drive  
Ann Arbor, MI 48103

Submitter's Name: Karen A. Lindner  
Phone: (734) 761-1990

### Device Name:

Proprietary name: Danmar Products Michigan Cranial Helmet

Common Name: Cranial Helmet

Classification Name: Cranial Orthosis

### Predicate Device Equivalence:

Substantial equivalence is claimed to the Cranial Technologies Dynamic Orthotic Cranioplasty - DOC Band®, cleared for commercial distribution through the approved evaluation of an automatic Class III designation.

### Device Description:

The Danmar Products Michigan Cranial Helmet is constructed with front and rear sections that are comprised of an inner, soft foam that is  $\frac{1}{8}$ " to  $\frac{1}{4}$ " thick, and an outer shell made of a semi-rigid plastic.

• Special Products for Special Needs Since 1968 •

(313) 761-1990 (800) 783-1998 Fax (313) 761-8977 e-mail: danmarpro@aol.com

**Intended Use:**

The Danmar Products Michigan Cranial Helmet is intended for prescription use to be used to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape in infants from 3 to 18 months of age, with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic- and brachycephalic-shaped heads.

**Comparison of Technological Characteristics:**

The Danmar Products Michigan Cranial Helmet has the same technological characteristics as the predicate device.

**Summary of Device Evaluation:**

The literature on this and similar devices demonstrates that the Danmar Products Michigan Cranial Helmet performs as intended. Biocompatibility data demonstrate that the devices inner lining is nonirritating and nontoxic.

**Conclusions:**

Based on the above, we concluded that the Danmar Products Michigan Cranial Helmet is substantially equivalent to a legally marketed predicate device and is safe and effective for its intended use.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 29 2001

Ms. Karen Lindner  
President  
Danmar Products, Inc.  
221 Jackson Industrial Drive  
Ann Arbor, Michigan 48103

Re: K003630  
Trade Name: Danmar Products Michigan Cranial Helmet  
Regulation Number: 882.5970  
Regulatory Class: II  
Product Code: MVA  
Dated: March 9, 2001  
Received: March 12, 2001

Dear Ms. Lindner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "C. M. Witten", with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and  
Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): \_\_\_\_\_

Device Name: \_\_\_\_\_

Indications For Use:

**Device Name:**



Danmar Products Michigan Cranial Helmet

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  (Optional Format 3-10-98)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K003630